

*Screening test (or initial test).* In drug testing, an immunoassay screen to eliminate “negative” urine specimens from further analysis. In alcohol testing, an analytic procedure to determine whether an employee may have a prohibited concentration of alcohol in a breath specimen.

*Secretary.* The Secretary of Transportation or the Secretary’s designee.

*Shipping container.* A container capable of being secured with a tamper-evident seal that is used for transfer of one or more urine specimen bottle(s) and associated documentation from the collection site to the laboratory.

*Specimen bottle.* The bottle that, after being labeled and sealed according to the procedures in this part, is used to transmit a urine sample to the laboratory.

*Substance abuse professional.* A licensed physician (Medical Doctor or Doctor of Osteopathy); or a licensed or certified psychologist, social worker, or employee assistance professional; or an addiction counselor (certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission or by the International Certification Reciprocity Consortium/Alcohol & Other Drug Abuse). All must have knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled substances-related disorders.

[59 FR 7354, Feb. 15, 1994, as amended at 59 FR 43000, Aug. 19, 1994; 61 FR 37224, July 17, 1996]

**§§ 40.5—40.19 [Reserved]**

**Subpart B—Drug Testing**

**§ 40.21 The drugs.**

(a) DOT agency drug testing programs require that employers test for marijuana, cocaine, opiates, amphetamines and phencyclidine.

(b) An employer may include in its testing protocols other controlled substances or alcohol only pursuant to a DOT agency approval, if testing for those substances is authorized under agency regulations and if the DHHS has established an approved testing protocol and positive threshold for each such substance.

(c) Urine specimens collected under DOT agency regulations requiring compliance with this part may only be used to test for controlled substances designated or approved for testing as described in this section and shall not be used to conduct any other analysis or test unless otherwise specifically authorized by DOT agency regulations.

(d) This section does not prohibit procedures reasonably incident to analysis of the specimen for controlled substances (e.g., determination of pH or tests for specific gravity, creatinine concentration or presence of adulterants).

**§ 40.23 Preparation for testing.**

The employer and certified laboratory shall develop and maintain a clear and well-documented procedure for collection, shipment, and accessioning of urine specimens under this part. Such a procedure shall include, at a minimum, the following:

(a)(1) Except as provided in paragraph (a)(2) of this section, use of the drug testing form prescribed under this part.

(i) This form is found in appendix A to this part.

(ii) Employers and other participants in the DOT drug testing program may not modify or revise this form, except that the drug testing custody and control form may include such additional information as may be required for billing or other legitimate purposes necessary to the collection, provided that personal identifying information on the donor (other than the social security number or other employee ID number) may not be provided to the laboratory.

(iii) Donor medical information may appear only on the copy provided the donor.

(2) Notwithstanding the requirement of paragraph (a)(1)(ii) of this section, employers and other participants may use existing forms that were in use in the DOT drug testing program prior to February 16, 1995, until June 1, 1995.

(b)(1) Use of a clean, single-use specimen bottle that is securely wrapped until filled with the specimen. A clean, single-use collection container (e.g., disposable cup or sterile urinal) that is securely wrapped until used may also

be employed. *If urination is directly into the specimen bottle*, the specimen bottle shall be provided to the employee still sealed in its wrapper or shall be unwrapped in the employee's presence immediately prior to its being provided. *If a separate collection container is used for urination*, the collection container shall be provided to the employee still sealed in its wrapper or shall be unwrapped in the employee's presence immediately prior to its being provided; and the collection site person shall unwrap the specimen bottle in the presence of the employee at the time the urine specimen is presented.

(2) Use of a tamperproof sealing system, designed in a manner such to ensure against undetected opening. The specimen bottle shall be identified with a unique identifying number identical to that appearing on the urine custody and control form, and space shall be provided to initial the bottle affirming its identity. For purposes of clarity, this part assumes use of a system made up of one or more preprinted labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which the specimen and associated paperwork may be transferred and which can be sealed and initialed to prevent undetected tampering. If the split specimen option is exercised, the split specimen and associated paperwork shall be sealed in a shipping (or storage) container and initialed to prevent undetected tampering.

(d) Written procedures, instructions and training shall be provided as follows:

(1) Employer collection procedures and training shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the donor, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for

collection under this part and certifies completion as required in this part

(i) A non-medical collection site person shall receive training in compliance with this part and shall demonstrate proficiency in the application of this part prior to serving as a collection site person. A medical professional, technologist or technician licensed or otherwise approved to practice in the jurisdiction in which the collection takes place is not required to receive such training if that person is provided instructions described in this part and performs collections in accordance with those instructions.

(ii) Collection site persons shall be provided with detailed, clear instructions on the collection of specimens in compliance with this part. Employer representatives and donors subject to testing shall also be provided standard written instructions setting forth their responsibilities.

(3) Unless it is impracticable for any other individual to perform this function, a direct supervisor of an employee shall not serve as the collection site person for a test of the employee. If the rules of a DOT agency are more stringent than this provision regarding the use of supervisors as collection site personnel, the DOT agency rules shall prevail with respect to testing to which they apply.

(4) In any case where a collection is monitored by non-medical personnel or is directly observed, the collection site person shall be of the same gender as the donor. A collection is monitored for this purpose if the enclosure provides less than complete privacy for the donor (e.g., if a restroom stall is used and the collection site person remains in the restroom, or if the collection site person is expected to listen for use of unsecured sources of water.)

[54 FR 49866, Dec. 1, 1989, as amended at 60 FR 19536, Apr. 19, 1995]

#### **§ 40.25 Specimen collection procedures.**

(a) *Designation of collection site.* (1) Each employer drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities and supervision to provide for the